UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

ELMER HEISNER, INDIVIDUALLY AND ON BEHALF OF, JAYNE HEISNER,
Plaintiff,

vs.

GENZYME CORPORATION, a Massachusetts Corporation,
Defendant.

08 C 593

JUDGE COAR
MAGISTRATE JUDGE DENLOW

COMPLAINT

NOW COMES the Plaintiff, ELMER HEISNER, Individually and on behalf of the deceased, JAYNE HEISNER, ("Plaintiff"), by and through his attorneys, THE LAW GROUP, LTD., and complaining of the Defendant, GENZYME CORPORATION, states as follows:

I. PARTIES

A. PLAINTIFF

1. Plaintiff, ELMER HEISNER, is a citizen and resident of the state of Illinois.

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2. The deceased, JAYNE HEISNER, was also a citizen and resident of Illinois. JAYNE HEISNER underwent surgery to remove an ovarian cyst on January 19, 2006. At that time a Seprafilm adhesion barrier was placed into her body to prevent potential postsurgical adhesions. Soon thereafter on February 22, 2006, JAYNE HEISNER died as a proximate result of the implanation of Seprafilm into her body. JAYNE HEISNER is survived by her husband ELMER HEISNER and her adult children: LAURA SCHMITZ, DAVID HEISNER, LINDA MCKIMMY, and CAROL HULSLANDER.

B. DEFENDANT

3. Defendant, GENZYME CORPORATION, is a Massachusetts Corporation with its principal place of business located at 500 Kendall Street, Cambridge, Massachusetts, 02142.

4. GENZYME is a life sciences company, whose core products include enzyme replacement therapy products, adhesion prevention, and other pharmaceutical products, including Seprafilm.

5. At all times relevant hereto, Defendant, GENZYME, was engaged in the business of designing, licensing, manufacturing, selling, marketing, distributing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, a medical device known as Seprafilm.

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II. JURISDICTION

6. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 (diversity jurisdiction) because the amount in controversy exceeds $75,000 exclusive of interest and costs, and because this is an action by an individual Plaintiff and Defendant who are each citizens of a different state.

7. GENZYME is a corporation headquartered in and a resident of the State of Massachusetts. Defendant has, therefore, subjected itself to personal jurisdiction and venue is proper in this District pursuant to 28 U.S.C. § 1391.

8. The Plaintiff, ELMER HEISNER, is a citizen and resident of the State of Illinois.

9. The deceased, JAYNE HEISNER, was a citizen and resident of the State of Illinois at the time of her death.

III. FACTUAL ALLEGATIONS

10. Seprafilm, manufactured by GENZYME, is intended to be a device used by medical professionals to prevent adhesions in those undergoing pelvic or laparotomy procedures by separating traumatized tissue surfaces after one undergoes pelvic and/or abdominal surgery. Adhesions are a dangerous condition that if left untreated can cause serious health risks, including death, to patients post surgical procedure.

11. An adhesion is an internal scar that may form after surgery on or

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between manipulated internal organs and/or body tissue. Adhesions between tissue can twist and pull organs out of their normal places.

12. Seprafilm Adhesion Barrier was approved by the United States Food and Drug Administration ("FDA") on December 20, 2000.

13. The FDA has published evidence of documented permanent injuries, including death, for those persons who have endured a surgical procedure and were given Seprafilm intended to prevent postoperative adhesions in the body.

14. Merely some of the adverse reactions of Seprafilm published by the FDA include: death, severe chronic inflammation of the small bowel area, small bowel obstruction, concrete abdomen, concrete intestines, adhesion of internal organs, dense fibroids, extremely high fever, severe adhesive intestinal obstruction, and vaginal bleeding.

IV. CLAIMS FOR RELIEF
COUNT 1
VIOLATION OF M.G.L. §2-314

15. Plaintiffs reallege and incorporate paragraphs 1-14 of this Complaint.

16. Seprafilm is a "good" as defined in M.G.L. §2-314(2).

17. GENZYME is a "merchant" as defined in M.G.L. §2-104(1).

18. To be merchantable, goods must, among other things, at least be fit

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for the ordinary purposes for which such goods are used.

19. GENZYME's defective Seprafilm was sold with the implied warranty of merchantability, meaning it would (a) pass without objection in the trade; (b) was fit for the ordinary purpose for which is was used; (c) would run of even kind, quality, and quantity within each unit and among all units involved; (d) was adequately contained, labeled, and packaged; and (e) conformed to GENZYME's promises or affirmations of fact made on its container and label.

20. By virtue of its defect, GENZYME's Seprafilm did not (a) pass without objection in the trade, in that it caused and had the propensity to cause concrete intestines; (b) was not fit for its ordinary purpose for which anti-adhesion products are used, in that it caused and had the propensity to cause concrete intestines; (c) did not run of even kind, quality, and quantity within each unit and among all units involved in that it caused and had the propensity to cause concrete intestines; (d) was not adequately contained, labeled, and packaged, in that it caused and had the propensity to cause concrete intestines; and, accordingly (e) did not conform to the promises or affirmation of fact made on its container and label as a product that solely prevents adhesions by separating traumatized tissue surfaces, in that it caused and had the propensity to cause concrete intestines.

21. As a proximate result of GENZYME's breach of the implied

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warranty of merchantability, Plaintiff suffered money damages.

COUNT II
VIOLATION OF GENERAL LAWS OF MASSACHUSETTS
CH. 93 A §2(a),et seq.

22. Plaintiff realleges and incorporates paragraphs 1-21of this Complaint.

23. GENZYME's advertising, marketing, and selling Seprafilm, while failing to disclose that it caused and had the propensity to cause concrete intestines, were unlawful, as proscribed by M.G.L. Ch. 93A §2(a), in that Defendant advertised, marketed, and sold its Seprafilm as a good that contained characteristics, ingredients, uses, or benefits that it did not have in that GENZYME's Seprafilm did not solely prevent adhesions by separating traumatized tissue surfaces, but rather caused and had the propensity to cause concrete intestines.

24. GENZYME's advertising, marketing, and selling its Seprafilm, while failing to disclose that it caused and had the propensity to cause concrete intestines, were unlawful, as proscribed by, M.G.L. Ch. 93A §2(a) in that GENZYME represented its Seprafilm as a good of a particular standard, quality, or grade that it did not possess in that GENZYME's Seprafilm had the propensity to cause concrete intestines.

25. GENZYME's advertising, marketing, and selling its Seprafilm, while

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failing to disclose that it caused and had the propensity to cause concrete intestines, were unlawful, as proscribed by M.G.L. Ch. 93A §2(a) , in that GENZYME engaged in fraudulent or deceptive conduct that created a likelihood of confusion or misunderstanding among Plaintiffs in that GENZYME's Seprafilm did not prevent adhesions, but rather, had the propensity to cause concrete intestines.

26. Plaintiff paid for Seprafilm that they would not have purchased had they known that Seprafilm caused and had the propensity to cause concrete intestines. Further, once GENZYME became aware of the fact that Seprafilm caused and had the propensity to cause concrete intestines, it failed to act quickly in alerting JAYNE HEISNER and other consumers of the product.

27. The deceased, JAYNE HEISNER, has been monetarily injured as a result of GENZYME's deceptive acts and unlawful practices as set forth in this Complaint.

28. As a proximate result of GENZYME's violations of M.G.L.§2-314 and 93A §2(a) , Plaintiff, ELMER HEISNER, is entitled to damages for all amounts paid to GENZYME for Defendant's Seprafilm, as well as disgorgement, interest, attorneys' fees, and costs.

COUNT III
STRICT LIABILITY PURSUANT TO §402A OF THE RESTATEMENT (SECOND) OF TORTS

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29. Plaintiff repeats and realleges, as if fully set forth herein, each and every allegation contained in the above paragraphs and further alleges:

30. The Defendant, from its headquarters in Massachusetts, made every and all decisions regarding the manufacturing, designing, testing, labeling, sterilizing, packaging, supplying, marketing, selling, advertising, warning, and otherwise distributing Seprafilm in the United States, which it sold and distributed throughout the United States to the doctors which implanted the device into the Decedent's body.

31. JAYNE HEISNER was using Seprafilm in a manner for which it was intended or in a reasonably foreseeable manner.

32. Seprafilm was expected to and did reach the Plaintiff without substantial change in its condition as manufactured, created, designed, tested, labeled, sterilized, packaged, supplied, marketed, sold, advertised, warned, and otherwise distributed.

33. The Plaintiff was not aware of, and reasonably could not have discovered, the dangerous nature of Seprafilm.

34. The Defendant's Seprafilm caused increased risks of concrete intestines, and therefore constitutes a product unreasonably dangerous for normal use due to its defective design, defective manufacture, and the GENZYME's misrepresentations and inadequate facts disclosed to the JAYNE HEISNER.

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35. As a direct and proximate result of GENZYME's decision making process, related to the manufacturing, creating, designing, testing, labeling, sterilizing, packaging, supplying, marketing, selling, advertising, warning, and otherwise distributing Seprafilm, JAYNE HEISNER suffered concrete intestines and died and consequently suffered compensatory and punitive damages in an amount to be proven at trial.

36. GENZYME, therefore, is strictly liable to the Plaintiff. Additionally, Defendant's conduct was so outrageous as to constitute ill will, bad motive and reckless indifference to the interests of the consumers. The Plaintiff, therefore, is entitled to punitive damages.

COUNT IV
NEGLIGENCE

37. Plaintiff repeats and realleges, as if fully set forth herein, each and every allegation contained in the above paragraphs and further alleges:

38 It was the duty of the Defendant to use reasonable care in the marketing, selling, advertising, warning, and otherwise distributing Seprafilm.

39 Contrary to its duty, the Defendant was guilty of one or more of the following careless and negligent acts and/or omissions:

(A). Failed to adequately and properly test and inspect Seprafilm so as to ascertain whether or not it was safe and proper for the purpose for which it was designed, manufactured and sold;

(B). Failed to utilize and/or implement a reasonably safe design in the manufacture of Seprafilm;

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(C). Failed to manufacture Seprafilm in a reasonably safe condition for which it was intended;

(D). Failed to adequately and properly warn Plaintiff purchasing Seprafilm of the risks of complications when used in a manner for which it was intended;

(E). Failed to adequately and properly warn Plaintiff purchasing Seprafilm of the risks of diseases when used in a manner for which it was intended;

(F). Failed to adequately and properly label Seprafilm so as to warn the Plaintiff of the risks of complications;

(G). Failed to adequately and properly label Seprafilm so as to warn the Plaintiff of the risks of concrete intestines;

(H). Manufactured Seprafilm which constituted a hazard to health;

(I). Manufactured Seprafilm which caused adverse side effects; and

(J). Were otherwise careless and negligent.

40. As a direct and proximate result of GENZYME's marketing, selling, advertising, and otherwise distributing Seprafilm, Plaintiff is at an increased risk of developing concrete intestines and has suffered compensatory and punitive damages in an amount to be proven at trial.

COUNT V
NEGLIGENCE PER SE

41. Plaintiff repeats and realleges, as if fully set forth herein, each and every allegation contained in the above paragraphs and further alleges:

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42. GENZYME had an obligation not to violate the law in the manufacture, design, formulation, compounding, testing, production, processing, assembly, inspection, research, distribution, marketing, labeling, packaging, preparation for use, sale and warning of the risks and dangers of Seprafilm.

43. GENZYME violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et seq., related amendments and codes and federal regulations provided thereunder, the Sherman Food, Drug and Cosmetic Law, and other applicable laws, statutes and regulations.

44. Plaintiff, as a purchaser and consumer of Seprafilm, is within the class of persons the statutes and regulations described above are designed to protect and Plaintiff's injury is of the type of harm these statutes are designed to prevent.

45. GENZYME's acts constitute an adulteration and/or misbranding as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 331 and constitutes a breach of duty subjecting GENZYME to civil liability for all damages arising therefrom, under theories of negligence per se.

46. GENZYME failed to meet the standard of care set by the following statutes and regulations, which were intended for the benefit of individuals such as the Plaintiff, making GENZYME negligent per se:

(A) The labeling lacked adequate information on the use of the product Seprafilm [21 C.F.R. Section 201.56(a) and (d);

(B) The labeling failed to provide adequate warnings of severe and disabling medical conditions including, without

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limitations, concrete intestines and other adverse medical conditions as soon as there was reasonable evidence of their association with the product [21 C.F.R. 201.57(e)];

(C) There was inadequate information for patients for the safe and effective use of GENZYME's product [21 C.F.R. 201.57(f)(2)];

(D) There was inadequate information regarding special care to be exercised by the doctor for safe and effective use of GENZYME's product [21 C.F.R. 201.57(f)(1)]; and

(E) The labeling was misleading and promotional [21 C.F.R. 201.56(b)].

47. As a result of the violations of the statutes described above, Plaintiff suffered injuries and damages as alleged herein.

COUNT VI
BREACH OF EXPRESS WARRANTY

48. Plaintiff repeats and realleges, as if fully set forth herein, each and every allegation contained in the above paragraphs and further alleges:

49. GENZYME expressly warranted to Plaintiff, by and through statements made by GENZYME or their authorized agents, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that Seprafilm was safe, effective, fit and proper for its intended use.

50. In using Seprafilm, Plaintiff relied on the skill, judgment, representations and foregoing express warranties of the GENZYME. Said warranties and representations were false in that the aforementioned product was not safe and was unfit for the uses for which it was intended.

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51. As a direct and proximate result of GENZYME's breach of warranty, JAYNE HEISNER was at an increased risk of developing concrete intestines and has suffered compensatory and punitive damages in an amount to be proven at trial.

COUNT VII
BREACH OF IMPLIED WARRANTY

52. Plaintiff repeats and realleges, as if fully set forth herein, each and every allegation contained in the above paragraphs and further alleges:

53. Prior to the time that Seprafilm was used by JAYNE HEISNER, GENZYME impliedly warranted to the deceased that Seprafilm was of merchantable quality and safe and fit for the use for which it was intended.

54. JAYNE HEISNER was and is unskilled in the research, design and manufacture of Seprafilm and reasonably relied entirely on the skill, judgment and implied warranty of GENZYME in using Seprafilm.

55. Seprafilm was neither safe for its intended use nor of merchantable quality, as warranted by GENZYME, in that it had dangerous propensities when put to its intended use and would cause severe injuries to the user.

56. As a direct and proximate result of GENZYME's breaches of warranties, JAYNE HEISNER died and her family, including her personal representative, ELMER HEISNER, suffered compensatory and punitive damages in an amount to be proven at trial.

PRAYER FOR RELIEF

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WHEREFORE, Plaintiff, ELMER HEISNER, by and through his attorneys, THE LAW GROUP, LTD., prays for relief as follows:

1. With respect to Count I, that this Court rule that GENZYME violated Massachusetts law and that compensatory damages are appropriate pursuant to M.G.L. §2-314 ;
2. With respect to Count II, that this Court rule that GENZYME violated Massachusetts law and that compensatory damages are appropriate pursuant to M.G.L. 93A §2(a).
3. For general damages in a sum in excess of the jurisdictional minimum of this Court;
4. Medical, incidental, hospital and service expenses according to proof;
5. Loss of earnings and earning capacity according to proof;
6. Prejudgment and post judgment interest as provided by law;
7. Compensatory damages in excess of the jurisdictional minimum of the Court, according to proof;
8. Consequential damages in excess of the jurisdictional minimum of the Court, according to proof;
9. Damages for the Wrongful Death of JAYNE HEISER pursuant to the Illinois Wrongful Death Act, 740 ILCS 180/1;
10. Damages awarded pursuant to the State of Illinois Survival Act, 740 ILCS 180/2;

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11. Damages for loss of consortium and society;

12. Punitive and exemplary damages;

13. Attorneys' fees, expenses and costs of this action; and

14. Such further relief as this Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a jury trial on all claims so triable in this action.

RESPECTFULLY SUBMITTED,

By: /s// Kurt D. Hyzy
Kurt D. Hyzy, #6196871
Pamela G. Sotoodeh, #6284622
Melissa A. Hunt, #6288265
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